

## REMARKS

### I. Status of Claims

Claims 1-3 are pending in the subject U.S. patent application. Claim 3 has been withdrawn as being directed to non-elected subject matter. The U.S. Patent and Trademark Office (hereinafter "the Patent Office") has examined claims 1 and 2 and they currently stand rejected.

Claims 1 and 2 and withdrawn claim 3 have been amended by the present amendment. New claim 4 has been added. Support for the amendments and new claim can be found in the application as filed. No new matter has been added.

### II. Claim Amendments

Claim 1 has been amended to recite a bactericide against *Streptococcus mutans* and *Streptococcus sobrinus* comprising (1) or (2): (1) a protein comprising SEQ ID NO: 1; or (2) a protein comprising SEQ ID NO: 1, wherein the protein is obtained from cultured cells transformed by DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1. Support for the amendment can be found in claim 1 as originally filed.

Claim 2 has been amended to recite a composition for treating or preventing tooth decay comprising the bactericide of claim 1. Support for the amendment can be found in claim 2 as originally filed.

Withdrawn claim 3 has been amended to recite a method for killing selectively *Streptococcus mutans* and *Streptococcus sobrinus* using (1) or (2): (1) a protein comprising SEQ ID NO: 1; or (2) a protein comprising SEQ ID NO: 1, wherein the protein is obtained from cultured cells transformed by DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1. Support for the amendment can be found in claim 3 as originally filed.

### III. Priority

Applicants respectfully submit that a copy of the English translation of the priority document, Japanese Patent Application No. 2003-419123, is being filed herewith, together with a statement of true and accurate translation. Consequently, applicant respectfully submits that they have perfected their claim to priority to Japanese Patent

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Application No. 2003-419123, and the instant application should thus be awarded a priority date of December 23, 2003.

IV. Response to Non-Statutory Obviousness-type Double Patenting Rejection

Claims 1 and 2 have been provisionally rejected on the grounds of non-statutory obviousness-type double patenting in view of claims 1-6 of co-pending U.S. Patent Application Serial No. 11/921,876 (hereinafter "the '876 Application"). In particular, the Patent Office contends that the copending claims are drawn to a bactericide comprising automutanolysin, which has 98.4% sequence homology with instantly claimed SEQ ID NO: 1.

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, applicants respectfully submit that, as described hereinabove, claim 1 has been amended to recite a bactericide against *Streptococcus mutans* and *Streptococcus sobrinus* comprising (1) or (2): (1) a protein comprising SEQ ID NO: 1; or (2) a protein comprising SEQ ID NO: 1, wherein the protein is obtained from cultured cells transformed by DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1. Claim 2 depends from claim 1 and therefore includes each and every element of claim 1.

Applicants respectfully submit that claims 1 and 2 are patentably distinct from the claims of the '876 Application. Applicants respectfully request that the provisional rejection of claims 1 and 2 on the grounds of non-statutory obviousness-type double patenting in view of the claims of the '876 Application be withdrawn and further ask that claims 1 and 2 be allowed at this time.

V. Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Patent Office contends that the specification discloses a single protein of SEQ ID NO: 1, which is encoded by SEQ ID NO: 2. However, the Patent Office contends that the species of SEQ ID NO: 1 is not representative of the genus of proteins having 95% sequence

homology to SEQ ID NO: 1 and that the specification does not provide guidance with regard to which 5% of SEQ ID NO: 1 can be altered while retaining the function related to lysing *S. mutans* and *S. sobrinus*. The Patent Office further contends that claim 1(3) is directed to any protein produced by the transformed cell and to any protein produced by a cell transformed by any nucleotide fragment of SEQ ID NO: 2

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, without acquiescing to the rejection or to the Patent Office's comments, applicants respectfully submit that, as noted hereinabove, claim 1 has been amended herein to recite a bactericide against *Streptococcus mutans* and *Streptococcus sobrinus* comprising (1) or (2): (1) a protein comprising SEQ ID NO: 1; or (2) a protein comprising SEQ ID NO: 1, wherein the protein is obtained from cultured cells transformed by DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1. Applicants respectfully believe that the written description requirement of 35 U.S.C. § 112, first paragraph, has been met with regard to claim 1, particularly in view of the Patent Office's remarks with regard to SEQ ID NO: 1. Applicants further respectfully believe that the rewording of claim 1(3), which is now claim 1(2), makes clear that the protein produced by the transformed cell is a protein comprising SEQ ID NO: 1, and that the cell was transformed with DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1.

Claim 2 depends from claim 1, and thus includes each and every element of claim 1. Thus, applicants respectfully submit that the written description requirement of 35 U.S.C. § 112, first paragraph has also been met with regard to claim 2.

Applicants respectfully request that the rejection of claims 1 and 2 under 35 U.S.C. § 112, first paragraph, be withdrawn and further ask that claims 1 and 2 be allowed at this time.

#### VI. Response to Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Patent

Office contends that claim 1 is vague because it is unclear how a protein can have a band in zymography and because it is unclear if "DNA encoding said protein (1)" refers to the protein of section (1) or section (3) of claim 1. The Patent Office further contends that claim 2 is indefinite because the Patent Office contends that the phrases "preventative agent of tooth decay" and "therapeutic agent of tooth decay" are unclear in that each still relates to an agent of tooth decay.

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, without acquiescing to the contentions of the Patent Office, applicants respectfully submit that the phrase "a protein having a 100±10kDa band of lysed bacteria in a zymography containing killed *Streptococcus mutans*" has been deleted from claim 1, thereby rendering the Patent Office's remarks regarding proteins not having bands moot.

Applicants further respectfully submit that, without acquiescing to the contentions of the Patent Office, claim 1 has been amended to recite "(2) a protein comprising SEQ ID NO: 1, wherein the protein is obtained from cultured cells transformed by DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1." Accordingly, applicants further respectfully submit that the Patent Office's comments regarding "said protein (1)" have been rendered moot.

Finally, applicants respectfully submit that in view of the rewording of claim 2, one of ordinary skill in the art would readily appreciate that claim 2 is directed to compositions for preventing or treating tooth decay, and not to agents that cause tooth decay.

Applicants respectfully submit that the Patent Office's remarks regarding the clarity of claim 1 and 2 have been addressed and that claims 1 and 2 meet the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, applicants respectfully request that the rejection of claims 1 and 2 under 35 U.S.C. § 112, second paragraph, be withdrawn and that claims 1 and 2 be allowed at this time.

VII. Response to Rejection under 35 U.S.C. § 102(a) over Yoshimura

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Yoshimura et al. (*Microbiol. Immunol.*, 48, 465-469 (2004); hereinafter "Yoshimura"). The Patent Office contends that Yoshimura discloses a bacteriolytic enzyme from *S. mutans* which creates a band of lysed bacteria in a zymography containing killed *Streptococcus mutans* at 100 kDa.

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Without acquiescing to the Patent Office's contentions regarding Yoshimura, applicants respectfully submit that the subject application claims priority to Japanese Patent Application No. 2003-419123, filed on December 23, 2003. As described hereinabove, an English translation of Japanese Patent Application No. 2003-419123 and a statement of true and accurate translation are being filed herewith. Thus, applicants respectfully submit that the subject application has an effective filing date that precedes the publication of Yoshimura. Accordingly, applicants respectfully request that Yoshimura be removed as a reference against the subject application and that the rejection of claims 1-2 under 35 U.S.C. § 102(a) over Yoshimura be withdrawn. Applicants further ask that claims 1-2 be allowed at this time.

VIII. Response to Rejection under 35 U.S.C. § 102(b) over Wang

Claims 1-2 have been rejected under 35 U.S.C. § 102(b) over PCT Publication No. WO 02/077183A2 to Wang et al. (hereinafter "Wang"). The Patent Office contends that Wang discloses a composition comprising a pharmaceutically acceptable carrier and a purified protein produced from a cell transformed with SEQ ID NO: 36377, which the Patent Office alleges is a nucleotide of presently recited SEQ ID NO: 2, because nucleotides 1-240 of SEQ ID NO: 36377 match nucleotides 2161-2400 of SEQ ID NO: 2.

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, without acquiescing to the contentions of the Patent Office, applicants respectfully submit that claim 1 has been amended to recite a bactericide against

*Streptococcus mutans* and *Streptococcus sobrinus* comprising (1) or (2): (1) a protein comprising SEQ ID NO: 1; or (2) a protein comprising SEQ ID NO: 1, wherein the protein is obtained from cultured cells transformed by DNA comprising SEQ ID NO: 2 or DNA encoding SEQ ID NO: 1. Applicants respectfully submit that Wang does not disclose, teach, or suggest a bactericide of claim 1.

Claim 2 depends from claim 1 and, thus, includes each and every element of claim. Therefore, applicants respectfully submit that claim 2 has also been distinguished from Wang.

Applicants respectfully request that the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) over Wang be withdrawn and further ask that claims 1-2 be allowed at this time.

#### IX. New Claim

New claim 4 has been added.

New claim 4 recites the composition of claim 2, wherein the composition is a toothpaste, an oral cavity cleaner, or a gum. Support for new claim 4 can be found in claim 2 as originally filed. No new matter has been added.

Applicants respectfully believe that new claim 4 is in order for allowance and respectfully request a Notice of Allowance to that effect.

#### CONCLUSIONS

Should there be any minor issues outstanding in this matter the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

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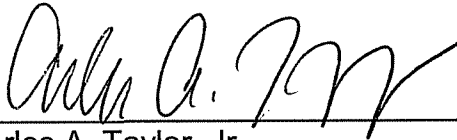
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any other fees associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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